

### **III. Remarks**

#### **A. Status of the Application**

Claims 1-4, 7, 9, 11, 14-18, 24-26, and 29-39 were previously pending. Claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34, and 39 are canceled by the present paper without prejudice to or disclaimer of the subject matter therein. New claims 40-54 are added by the present paper. Reconsideration of the application is respectfully requested in light of the above amendments and the following remarks.

#### **B. Claim Rejections Under 35 U.S.C. §102**

Previously pending claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34, and 39 were rejected under 35 U.S.C. § 102(b) as being anticipated by one or more of U.S. Patent Application Publication No. 2002/0082701 to Zdeblick et al. ("the Zdeblick application"), U.S. Patent No. 5,314,485 to Judet ("the Judet patent"), U.S. Patent No. 5,507,821 to Sennwald et al. ("the Sennwald patent"), and U.S. Patent Application Publication No. 2003/0045939 to Casutt et al. ("the Casutt application"). As claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34, and 39 are canceled by the present paper, these rejections are moot and will not be addressed at this time.

#### **C. Claim Rejections Under 35 U.S.C. §103**

Previously pending claims 35-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Casutt application. Applicants respectfully traverse the rejection of these claims on the grounds that the Casutt application is defective in establishing a *prima facie* case of obviousness.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."

*Id.* At 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness...

In the present application, a *prima facie* case of obviousness does not exist with respect to claims 31-39 for at least the reasons set forth below.

First, with respect to amended independent claim 35 the Casutt application does not appear to disclose, “a center member positioned at least partially between the first member and the second member and in sliding articulating engagement with the first and second members ... wherein the first member, second member, and center member are formed of a relatively rigid biocompatible material such that at least the third and fourth surfaces of the center member are not deformed by the sliding articulating engagement between the center member and the first and second members,” as recited. In that regard, the artificial intervertebral disc B includes “two end plates (1, 2) which bound a hollow space (4), which is filled with an **elastically and/or plastically deformable** nucleus (3), at two opposite sides, with the hollow space (4) being enclosed by a tubular fibre ring (5).” Abstract (emphasis added). That is, the artificial intervertebral disc B functions by deformation or compression of the nucleus (3) and the “fibre” ring (5). There is simply no disclosure of the end plates (1, 2) being in sliding articulating engagement with the nucleus (3) without deformation of the surfaces of the nucleus as required by independent claim 35. Further, one skilled in the art would not modify the nucleus to be a rigid material because “[t]he elastic behaviour of the artificial intervertebral disc of the invention is in this respect determined by the materials encompassing the fibre ring and the nucleus.” Paragraph [0009].

Also, no reason—other than hindsight based on the present invention—has been provided for modifying the Casutt application to include the limitations recited in these dependent claims. In that regard and as noted above, *KSR* notes that it is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. Clearly, changing the structural profile of the artificial intervertebral disc of the Casutt application to include a circular/cylindrical periphery as suggested by the Office Action would change both the structure and the resulting kinematic

properties of the disc. Further, the Casutt application notes that “[i]t is decisive for the function of the artificial intervertebral disc that the nucleus formed in this way preferably completely fills up the hollow space which the cover plates form with the fibre ring.” Paragraph [0010] Since the nucleus is filled as a fluid, its shape is defined by the cover plates and the fiber ring.

Accordingly, **changing the shape of the nucleus requires changing the shape of every component of the device.** Such substantial structural changes to the disclosed disc cannot be considered “a mere change in the shape of the component” as suggested by the Office Action.

Thus, for at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 35. Claims 36-38 and 40-44 depend from and further limit claim 35. Accordingly, claims 35-38 and 40-44 are patentable over the Casutt application and Applicants request that the §103 rejection of claims 35-38 over the Casutt application be withdrawn.

#### **D. New Claims**

New claims 40- are added by the present paper and recite combinations of limitations not disclosed or suggested by the cited references. Accordingly, Applicants believe that all of the new claims are patentable over the cited references.

#### **IV. Conclusion**

It is believed that all of the pending claims are in condition for allowance. Should the Examiner deem that any further amendment is necessary to place this application in condition for allowance, the Examiner is invited to contact the undersigned attorney at the telephone number noted below.

Respectfully submitted,



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